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DOCKET NO. D-2804CON2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Beck, et al.

Group Art Unit: 1614

Serial No: 10/800,992

Examiner: Jagoe, Donna

Filed: March 15, 2004

Confirm No. 2049

For: PRESERVED CYCLODEXTRIN-
CONTAINING COMPOSITIONS

DECLARATION OF KEN CHOW, Ph.D.

Dear Sir,

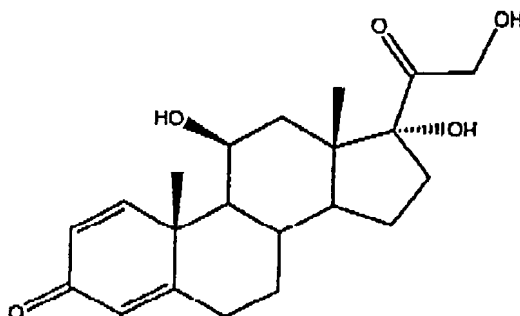
I, Ken Chow, Ph.D., hereby declare as follows:

1. I, Ken Chow, received a B.A. in Chemistry from the University of California, Berkeley in 1981, an M.S. degree in Chemistry from San Diego State University in 1983, and a Ph.D. in Organic Chemistry from the University of California, Irvine in 1988. I was awarded a postdoctoral fellowship at Yale University from 1988-1990, where my research involved the synthesis of prostaglandin PGF₂ α and nucleosides.
2. I have been employed at Allergan, Inc. since 1990, where I presently hold the title of Senior Research Investigator in the Synthetic Chemistry Department.
3. I understand that claims 31-50 of the above-referenced patent application are under rejection as being allegedly unpatentable pursuant to 35 U.S.C. §103(a) in light of Loftsson et al., U.S. Patent No. 5,472,954 in view of Dziabo et al., U.S. Patent No. 5,424,078. I also understand that the present claims are drawn to a prednisolone acetate composition, while Loftsson discusses prednisolone compositions.
4. I further understand that the rejection of the claims is predicated on the Examiner's assertion that the term "prednisolone" refers to a "small genus of compounds" rather than a single compound.
5. The ordinarily skilled chemist would understand the term "prednisolone" to refer to the single compound 1,4-pregnadiene-3,20-dione-11 β ,17 α ,21-triol, having a molecular weight of 360.44 Daltons, a decomposition temperature of 240-241 °C, which is very slight solubility in water. This alcohol has the following structure:

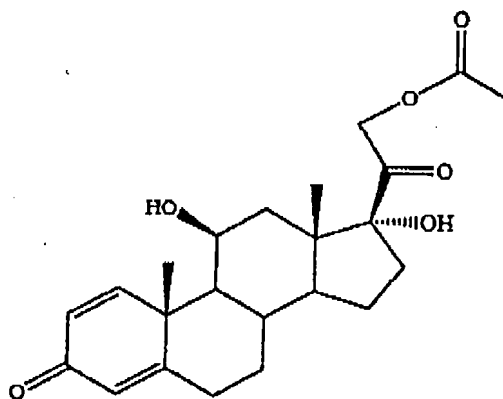
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6. The ordinarily skilled chemist would understand the term "prednisolone acetate" to refer to the single compound 11- β , 17- α , 21-trihydroxy-1,4-pregnadiene-3,20-dione 21-acetate, having a molecular weight of 402.48 Daltons, and a decomposition temperature of 237-239 °C, which is almost insoluble in water. The structure of this compound is as follows:



7. Thus, the person of ordinary skill in the art of medicinal chemistry would understand that prednisolone and prednisolone acetate are two different compounds, and that prednisolone does not refer to a genus, but to a specific compound. Evidence supporting this fact is provided in Exhibit A to this Declaration, which consists of a printout downloaded May 23, 2007 from the U.S. Food and Drug Administration's Orange Book web site, which lists approved prescription drugs by their active

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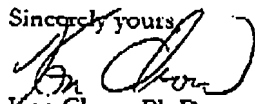
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ingredients. Exhibit A clearly and unambiguously indicates that products containing the active single ingredient "prednisolone" have received marketing approval in oral (syrup and tablet) formulations, but not for ophthalmic formulations, while products containing the distinct single compound "prednisolone acetate" have received marketing approval in suspension and ointment formulations for topical ophthalmic use, but not for oral formulations.

8. Therefore it is my opinion that the person of ordinary skill in the field of medicinal chemistry would clearly regard prednisolone as a single species and not a genus of compounds.
9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,


Ken Chow, Ph.D.
Principal Scientist